K110847

Summary of Safety and Effectiveness

JUL 15 2011

Date: March 14, 2011

Manufacturer:
Limacorporate S.p.A.
Via Nazionale, 52
33038 – Villanova di San Daniele
Udine - Italy

U.S. Contact Person:
Cheryl Hastings
Principal Consultant
Phone: 574-527-4220

Product	Product Code	Regulation and Classification Name
SMR CTA Humeral Heads	HSD	Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis per 21 CFR 888.3690
	KWS	Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Description:

The SMR CTA Humeral Heads are made from CoCrMo (ISO 5832-12 / ASTM F1537). They are intended to articulate with the glenoid bone (in hemi-arthroplasty) or with the glenoid component (total arthroplasty). The articulating surface is polished. The only difference between the SMR CTA Humeral Heads and the humeral heads cleared in K100858 is the addition of a lateral flange to better accommodate the rotator cuff tear arthropaty patient.

The SMR CTA Humeral Heads are intended to be coupled to the humeral body by means of specific adaptor tapers. Humeral bodies are then assembled by taper coupling with humeral stems. When used in total shoulder replacement, the SMR CTA Humeral Heads are coupled with glenoid components. Humeral stems, humeral bodies, adaptor tapers and glenoid components are the same cleared in K100858 and K101263.

SMR CTA Humeral Heads can be used with both cemented and uncemented stems. Glenoid components are intended for cemented use only.

The device descriptions for the adaptor tapers, humeral bodies, humeral stems and glenoid components cleared via K100858 and K101263 are repeated here in italic typing for an understanding of the complete system.

Two designs of humeral stems are available: the first one is intended for uncemented use while the second one is intended for cemented use only.

Two lengths of uncemented humeral stems are available: 60 and 80 mm. The 60 mm stems are characterized by an outline with a double conicity and they are finned to provide optimal proximal fixation. The stem is sand-blasted. The 80 mm stems are characterized by an outline with a triple conicity and are also finned to provide optimal proximal fixation. The proximal part is sand-blasted while the distal part is polished. All stems are made from Ti6Al4V (ISO 5832-3, ASTM F1472). The stems are provided with a male Morse taper (identical to that described in K100858) to allow coupling with the humeral bodies.

Humeral bodies are available in two designs. The first one is characterized by holes for humeral bone reconstruction as a consequence of trauma while the second one is finned to allow proximal press-fit fixation of the humeral system. Both designs of humeral bodies can be used in cemented and in uncemented applications. Humeral bodies are made from Ti6Al4V (ISO 5832-3, ASTM F1472).
They are coupled with the humeral stem via a female Morse-taper connection stabilized with a locking screw. Cylindrical marks are designed at the base of this Morse-taper to provide correct alignment of the eccentricity of the humeral head during surgery. A male Morse-taper connection is designed for the coupling between the humeral body and the humeral head by means of specific adaptor tapers: an angle of 45° between the axis of this Morse-taper and the axis of the stem gives the correct varus-valgus alignment to the joint.

Adaptor tapers (neutral and eccentrical with different heights), are made from Ti6Al4V (ISO 5832-3, ASTM F1472). They allow coupling between the humeral body and the humeral head. These devices are designed to adjust the centre of rotation of the joint and to give the required offset to the humeral head in order to achieve the correct tensioning to the soft tissues, optimizing joint stability.

The humeral heads are made from CoCrMo (ISO 5832-12, ASTM F1537). They are intended to articulate with the glenoid bone (in hemi-arthroplasty) or with the glenoid component (total arthroplasty). The surface is polished in order to reduce wear.

Glenoids are manufactured from Ultra-High Molecular Weight Polyethylene (UHMWPE ISO 5834-2, ASTM F648). The articulating surface has a radius of curvature greater than the corresponding humeral head. This allows translation in the superior/inferior and anterior/posterior directions. The back surface of the component is spherical in geometry and has a single central peg which is inserted in the hole drilled in the glenoid cavity during surgery. The peg surface has three grooves to provide enhanced cement fixation. Six cement pockets are also incorporated on the back surface of the glenoid to enhance cement fixation.

Intended Use: The SMR CTA Humeral Heads are intended for use with cemented and uncemented SMR humeral body – humeral stem assemblies in total or hemi- shoulder joint arthroplasty. The Glenoid is intended for cemented use only.

K110847

Total and hemi-shoulder replacement utilizing the CTA head is indicated for patients suffering from disability due to:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Inflammatory degenerative joint disease such as rheumatoid arthritis;
- Treatment of acute fractures of the humeral head that cannot be treated with other fracture fixation methods;
- Cuff tear arthropathy.

Predicate Devices:
SMR Shoulder System (Limacorporate, K100858) and SMR Uncemented Shoulder System (Limacorporate, K101263);
Global Advantage Extended Humeral Heads (DePuy, K000575).

Comparable Features to Predicate Device(s):
The SMR CTA humeral heads are similar to the predicate devices in terms of intended use, indications, design and materials. The CTA humeral heads and the predicates are all intended for partial or total primary shoulder joint replacement. The CTA humeral heads are intended for cemented or uncemented use, depending on the components they're coupled with (i.e. cemented or uncemented stems).

The design of CTA humeral heads is the same as the Global Advantage Extended Humeral Heads.

The components of the SMR CTA humeral heads are manufactured from the same materials as the predicate devices.

Non-Clinical Testing:
The SMR CTA humeral heads have the same modular coupling of the Standard humeral heads cleared via K100858. The modular connection has undergone static pull-out testing. All mechanical testing was done on worst case components or constructs. Where possible, standard test methods were used to allow comparison to testing of the predicate devices. A simulation of the Range of Motion has been performed to ensure the device design does not overly limit range of motion. The testing results demonstrated the device's ability to perform under expected clinical conditions.

Clinical Testing: Clinical testing was not necessary to demonstrate substantial equivalence of the SMR CTA Humeral Heads to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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JUL 15 2011

Re: K110847
Trade/Device Name: SMR CTA Humeral Heads
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD
Dated: June 20, 2011
Received: June 28, 2011

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110847

510(k) Number (if known): Unknown

Device Name: SMR CTA Humeral Heads

Indications for Use:

SMR CTA Humeral Heads
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The SMR CTA Humeral Heads are intended for use with cemented and uncemented SMR humeral body – humeral stem assemblies in total or hemi- shoulder joint arthroplasty. The Glenoid is intended for cemented use only.

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- Cuff tear arthropathy.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110847